CHOOSTENT ™

COVERED ESOPHAGEAL STENT

ENGLISH

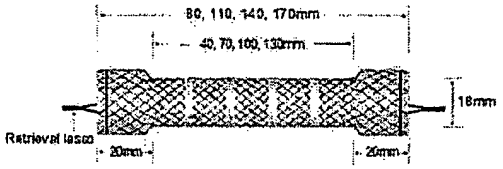
■ Please read these instructions carefully prior to use !
■ For single use only!

Indications for use

This stent is indicated for palliative treatment or upper gastrointestinal neoplasm in patients with unresectable esophageal, gastric carcinoma and also in pre-operative patients for correction of dysphagia and malnutrition during tumor reduction treatments such as cytostatic agent and/or radiation therapy, prior to planned surgery for removal of the esophagus. The stent is also indicated for the patients suffering from dysphagia due to extrinsic compression of the esophageal lumen by malignant esophageal tumors. Since the stent is fully covered with a membrane, it can be used for the patients suffering from the esophagotracheal fistula.

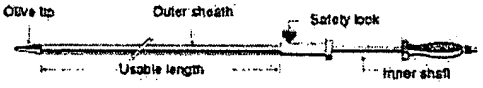
Stent Descriptions

This stent is a self-expanding tubular prosthesis designed to maintain patency of esophageal strictures caused by malignant tumors. The unique structure of the membrane connects the several separated segments to increase the flexibility of the stent and to prevent migration and tumor ingrowth. Since the both ends of stent have larger bands, the stent can be fixed firmly within the esophagus. There are totally 12 excellent radiopaque markers made of gold wires ; 4 each on both ends of the stent and another 4 on the center. Two retrieval lassos attached to the both ends play a role in removing the stent when necessary or pulling the stent up to the right position in case the stent has been deployed deeply down the stricture. The fully expanded diameter is 18mm for the body and 24mm for both larger bands. There are four standard lengths : 80, 110, 140, and 170mm. Various lengths are available.



Delivery Device Descriptions

1. The delivery device is composed of inner shaft, outer sheath having a safety lock, olive tip and inner tube which fits the olive tip in the distal end of the inner shaft.
2. The proximal part of inner shaft is reinforced by a stainless steel tube.
3. The safety lock prevents an accidental movement of the stent while the delivery device is advanced over the guidewire. To deploy the stent, loosen the safety lock by turning it counterclockwise before pulling the outer sheath backwards.
4. There is an excellent radiopaque marker made of stainless steel ring on the distal end of the inner shaft.
5. The delivery device allows a 0.038" super stiff guidewire.
6. The usable length of the delivery device is 70cm.



Precautions

1. This device should be used only by physicians who are familiar with and experienced in stenting technique and post-stenting patient care.
2. This device is sterilized. Do not use any device if its package was open or damaged. Non-sterile device should not be used for clinical purpose.
3. Inspect the device carefully prior to use to verify that the device has not been damaged during shipment and that its size and condition are suitable for the selected procedure.
4. Keep devices at normal temperature and avoid direct sunlight. Follow the first-in-first-out rules and do not use expired products.
5. Deployment of stents should be performed only under the fluoroscopic or endoscopic guidance.
6. Do not advance a partially deployed stent.
7. The stent can be removed by pulling a retrieval lasso with forceps in case the stent was mistakenly deployed deeply down the stricture.
8. If the stent should be deployed on esophagogastric junction, always maintain the patient's head at least 30 upwards to avoid the possible aspiration pneumonia caused by reflux even while sleeping.

Potential complications

- Bleeding
- Pain
- Stent migration
- Tumor overgrowth
- Foreign body sensation
- Edema
- Ulceration
- Fever
- Death(other than that due to normal disease progression)
- Perforation

Selections and Preparations

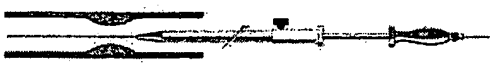
1. Choose the stent with optimum diameter and length after measuring and monitoring the length of the stricture using fluoroscope or endoscope.
2. Choose the stent which is at least 4cm longer in full length than the actual stricture. This will prevent the risk of tumor overgrowth which may occur later.
3. Make sure that the safety lock is locked firmly.
4. Maintain the delivery device as straight as possible outside the body..

Procedures

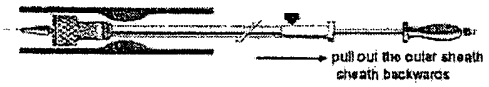
1. Insert a 0.038" super stiff guidewire fully across the stricture. If necessary, a balloon catheter or bougie dilator may be used first to expand stricture before stenting.
2. Advance the delivery device carefully over the guidewire until the end of stent is placed at least 2cm below the tumor after making sure that the inner shaft has been completely fixed by the safety lock.
3. Loosen the safety lock by turning it counterclockwise after checking the location of the stent.
4. Deploy the stent by pulling outer sheath slowly while maintaining the location of the inner shaft until the first segment expands.
5. Move the whole delivery devices carefully, approximately 3mm backwards under the fluoroscopic guidance and then pull the outer sheath until the second segment expands.
6. Repeat 4 and 5 until the stent expands fully. This method allows the stent to be properly positioned without overlapping each segment which is connected by flexible membrane.
7. Remove the delivery device carefully when the expansion of the stent has been confirmed. The olive tip is not necessary to remove.

Deployments

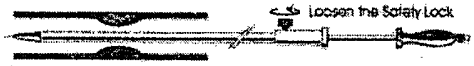
1. At first, make sure that the inner shaft has been completely fixed by safety lock and advance the delivery device over the guidewire across the stricture



2. Loosen the safety lock fully by turning it counterclockwise when the delivery device is located at the stricture.

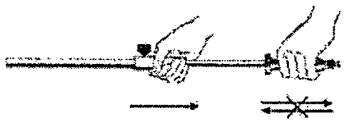


3. Immobilize the inner shaft by holding it firmly with one hand and then gently pull out the outer sheath backwards.



Caution

Do not push the inner shaft when you deploy the stent. The inner shaft must be held securely and not be allowed to move. Pushing the inner shaft will cause misalignment of the stent and possible damage to the esophagus.



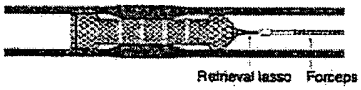
Caution

When withdrawing of the outer sheath is interrupted, stop pulling and wait for a while. If the situation does not get better, remove the whole delivery device and try it again from the first step.

4. After stent placement has been completed, withdraw the delivery device carefully

Repositioning Techniques

If the stent was mistakenly deployed deeply down far from the stricture, insert a forceps through the working channel of endoscope and carefully pull the lasso attached to the proximal end from the stricture in order to reposition the stent on the proper location.



Caution

The stent should be in place by pulling the endoscope repeatedly holding the lasso with forceps. Be careful that the stent should not be pulled up from the stricture.

Retrieval systems

Pull the lasso attached to the proximal bend by forceps through the working channel of
the endoscope. Retrieve the stent by removing the endoscope with the forceps.

Caution

The alligator type of forceps may cause the lasso to be cut off. It is recommended to use a rat's tooth type of forceps.

Sterilization

This device is sterilized with Ethylene Oxide

Warranty

M.I.Tech Co., Ltd. warrants that this product has been manufactured by the appropriate procedures. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, which are beyond M.I.Tech Co., Ltd.'s control such as warranties implied to the application of law, sales or specialty purposed suitability after handing over, storage, cleaning and sterilization of this product as well as matters related to the patient, diagnosis, treatment, surgical procedures and any other cause. M.I.Tech Co., Ltd. shall not be liable for any incidental, or consequential loss, damage or expense directly or indirectly arising from the use of this product other than the replacement of it. M.I.Tech Co., Ltd. shall neither take any additional responsibility nor authorize such responsibility or duty to other person related to this product.